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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/832,501	04/12/2001	David J. Ballance	6832.0012-00	2463

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HUMAN GENOME SCIENCES INC
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EXAMINER	
ROBINSON, HOPE A	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 11/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/832,501	BALLANCE ET AL.	
	Examiner	Art Unit	
	Hope A. Robinson	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-60* is/are pending in the application.

4a) Of the above claim(s) *22-60* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's election with traverse of Group I (claims 1-21) is acknowledged. The traversal is on the ground(s) that the claims not be restricted because no serious burden exists. Applicant states that search and examination of the subject matter of Group I would encompass a search for the subject matter of Group II and IV and any additional search would not impose a serious burden upon the examiner. This statement made by applicant appears to be contradictory as it is first stated that no additional search would be required and then concluded that any additional search would not be a burden. This argument is also not persuasive because the MPEP states that restriction requirement is proper if the inventions are independent or distinct. Applicant is not disputing the fact that the invention is independent or distinct, only that there is no search burden. MPEP 806.04 states that "if it can be shown that the two or more inventions are in fact independent, applicant should be required to restrict the claims presented to but one of such independent inventions. Additionally, note that the inventions have acquired a separate status in the art, which demonstrates burden of search. In addition burden of search can be exemplified with the results of a search conducted in the patented files which indicates that classification 536/23.1 (Group IV) has 1475 patents and classification 514/12 (Group II) has 3807 patents. Thus, the restriction requirement is proper and final.

2. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found

allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does

not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Basis For Statutory Double Patenting

3. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

4. Claims 1-21 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-21 of copending Application No. 09/833,117. The claims in both applications have the same language, scope, wording and subject matter. Both applications claim an albumin fusion protein comprising a therapeutic protein: X and albumin comprising the amino acid sequence of SEQ ID NO: 18. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

5. Claims 1-21 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-21 of copending Application No. 09/833,111. The claims in both applications have the same language, scope, wording and subject matter. Both applications claim an albumin fusion protein comprising a therapeutic protein: X and albumin comprising the amino acid sequence of SEQ ID NO: 18. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

6. Claims 1-21 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-21 of copending Application No. 09/833,118. The claims in both applications have the same language, scope, wording and subject matter. Both applications claim an albumin fusion protein comprising a therapeutic protein: X and albumin comprising the amino acid sequence of SEQ ID NO: 18. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

7. Claims 1-21 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-21 of copending Application No. 09/832,929. The claims in both applications have the same language, scope, wording and subject matter. Both applications claim an albumin fusion protein comprising a therapeutic protein: X and albumin comprising the amino acid sequence of SEQ ID NO: 18. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

8. Claims 1-21 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-21 of copending Application No. 09/832,041. The claims in both applications have the same language, scope, wording and subject matter. Both applications claim an albumin fusion protein comprising a therapeutic protein: X and

albumin comprising the amino acid sequence of SEQ ID NO: 18. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.
>
> (g)(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.
>
> (f) he did not himself invent the subject matter sought to be patented.
>
> The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).
>
> The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

9. Claims 1-21 are directed to the same invention as that of claims 1-21 of copending Application No. 09/833,118 that are commonly assigned . The issue of

priority under 35 U.S.C. 102(g) and possibly 35 U.S.C. 102(f) of this single invention must be resolved.

Since the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302), the assignee is required to state which entity is the prior inventor of the conflicting subject matter. A terminal disclaimer has no effect in this situation since the basis for refusing more than one patent is priority of invention under 35 U.S.C. 102(f) or (g) and not an extension of monopoly.

Failure to comply with this requirement will result in a holding of abandonment of this application.

10. Claims 1-21 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter of copending Application No. 09/833,118. The claims in both applications have the same language, scope, wording and subject matter. Both applications claim an albumin fusion protein comprising a therapeutic protein: X and albumin comprising the amino acid sequence of SEQ ID NO: 18. However, the applications have different inventive entity with common ownership.

11. Claims 1-21 are directed to the same invention as that of claims 1-21 of copending Application No. 09/833,111 that are commonly assigned . The issue of

priority under 35 U.S.C. 102(g) and possibly 35 U.S.C. 102(f) of this single invention must be resolved.

Since the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302), the assignee is required to state which entity is the prior inventor of the conflicting subject matter. A terminal disclaimer has no effect in this situation since the basis for refusing more than one patent is priority of invention under 35 U.S.C. 102(f) or (g) and not an extension of monopoly.

Failure to comply with this requirement will result in a holding of abandonment of this application.

12. Claims 1-21 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter of copending Application No. 09/833,111. The claims in both applications have the same language, scope, wording and subject matter. Both applications claim an albumin fusion protein comprising a therapeutic protein: X and albumin comprising the amino acid sequence of SEQ ID NO: 18. However, the applications have different inventive entity with common ownership.

13. Claims 1-21 are directed to the same invention as that of claims 1-21 of copending Application No. 09/832,929 that are commonly assigned . The issue of priority under 35 U.S.C. 102(g) and possibly 35 U.S.C. 102(f) of this single invention must be resolved.

Since the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302), the assignee is required to state which entity is the prior inventor of the conflicting subject matter. A terminal disclaimer has no effect in this situation since the basis for refusing more than one patent is priority of invention under 35 U.S.C. 102(f) or (g) and not an extension of monopoly.

Failure to comply with this requirement will result in a holding of abandonment of this application.

14. Claims 1-21 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter of copending Application No. 09/832,929. The claims in both applications have the same language, scope, wording and subject matter. Both applications claim an albumin fusion protein comprising a therapeutic protein: X and albumin comprising the amino acid sequence of SEQ ID NO: 18. However, the applications have different inventive entity with common ownership.

15. Claims 1-21 are directed to the same invention as that of claims 1-21 of copending Application No. 09/833,041 that are commonly assigned . The issue of priority under 35 U.S.C. 102(g) and possibly 35 U.S.C. 102(f) of this single invention must be resolved.

Since the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302), the assignee is required to state which entity is the prior inventor of

the conflicting subject matter. A terminal disclaimer has no effect in this situation since the basis for refusing more than one patent is priority of invention under 35 U.S.C. 102(f) or (g) and not an extension of monopoly.

Failure to comply with this requirement will result in a holding of abandonment of this application.

16. Claims 1-21 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter of copending Application No. 09/833,041. The claims in both applications have the same language, scope, wording and subject matter. Both applications claim an albumin fusion protein comprising a therapeutic protein: X and albumin comprising the amino acid sequence of SEQ ID NO: 18. However, the applications have different inventive entity with common ownership.

17 Claims 1-21 are provisionally rejected under 35 U.S.C. 102(e) as being anticipated by copending Application Nos. 09/833,111; 09/832,929; 09/833,118 and 09/832,041 which have a common ownership with the instant application.

Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e), if patented. This provisional rejection under 35 U.S.C. 102(e) is based upon a presumption of future patenting of the copending application.

This provisional rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

This rejection may not be overcome by the filing of a terminal disclaimer. See *In re Bartfeld*, 925 F.2d 1450, 17 USPQ2d 1885 (Fed. Cir. 1991).

18. Claims 1-3, 5-10, 13-14 and 17-21 are rejected under 35 U.S.C. 102 (b) as being anticipated by DELTA BIOTECHNOLOGY LTD. (WO 97/24445, July 10, 1997 or KR99076789, October 15, 1999).

DELTA BIOTECHNOLOGY LTD. disclose serum albumin fusion proteins comprising the sequence set forth in SEQ ID NO: 18 of the instant application with a 100% sequence identity (claim 1, see the sequence alignment and page 1 of the reference). Additionally, the reference discloses that the albumin is useful as a component of a fusion protein because it is a stabilizer and transporter of other proteins (page 1) and that the fusion proteins have an increased circulatory half-life (shelf-life) over unfused proteins (claim 2, page 3). The fusion protein of the claimed invention comprises "therapeutic protein X and albumin and the disclosure on page 2 indicates that the therapeutic protein is a polypeptide, antibody, peptide, fragments or variants thereof. As the reference discloses the fusion of albumin with a growth hormone described as a single polypeptide (page 2), by definition in the instant application the growth hormone fusion partner is a therapeutic protein. DELTA BIOTECHNOLOGY LTD. discloses that the half-life (shelf-life) of the fusion protein is greater than the half-life of fusion partner by itself. Additionally, the reference teaches that activity assays showed that the conjugate retained full, and possibly increased activity *in vitro* ((claim 3, page 3). It is disclosed that fusion to the polypeptide is achieved by genetic manipulation such that the DNA coding for HSA or a fragment thereof is joined to the DNA coding for said polypeptide (claim 5 and page 2 of the instant specification, page 1 of the reference). The reference discloses fragments/variants thereof of SEQ ID NO: 18

(claim 6, page 3). Further, as claim 6 recites the open language of comprising and the reference discloses the entire sequence set forth in SEQ ID NO: 18, the claimed fragments are anticipated. Regarding claims 7, 8, 9 and 10 which depend from claims 5 and 6, however encompass the limitation that a portion of albumin is sufficient to prolong the shelf-life (half-life), these claims are also anticipated by the reference which discloses the limitation of claims 5 and 6 and teach biologically active fragments of albumin having the activity of increasing the half-live (page 3).

DELTA BIOTECHNOLOGY LTD. discloses fusion proteins that are non-glycosylated (claim 13, page 2). The reference also discloses expression in *S. cerevisiae* (yeast) as recited in claim 14 (pages 2, 4). It is also stated that expression can occur in animal cells in culture (claims 17-18, page 8). The reference discloses a leader sequence (claim 19, page 17). A composition comprising the albumin fusion protein coupled with an acceptable carrier is disclosed (claim 20, page 12). Regarding claim 21 and the recitation of a kit comprising the composition, the reference teaches a pharmaceutical formulation comprising the fusion protein with one or more acceptable carrier presented in a unit dosage form which is equivalent to a kit (page 12). Therefore, as the structure of the protein in the reference is identical to that of the instant application and the reference discloses albumin fusion proteins and fragments thereof with increased albumin activity, the limitations of the claims are met by this reference.

Conclusion

19. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope Robinson whose telephone number is (703) 308-6231. The examiner can normally be reached on Monday-Friday from 9:00 am to 5:30 pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S.F. Low, can be reached at (703) 308-2923.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-2742. Please affix the examiner's name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Hope Robinson, MS

Patent Examiner

Christopher S. F. Low

CHRISTOPHER S. F. LOW
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